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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/035,963 | 11/09/2001 | HelenE Richardson | 10806-146 | 3794 |
| 24256 | 7590 | 11/22/2004 | EXAMINER | |
| DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202 | | | FAY, ZOHREH A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/035,963 | RICHARDSON ET AL. | |
| | Examiner | Art Unit | |
| | Zohreh Fay | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-32,34-37 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-32, 34-37 and 76-80 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claims 1-3, 5-32, 34-37 and 76-80 are presented for examination.

The amendments and remarks filed on January 21, 2004 have been received and entered.

There has been an inadvertent error in withdrawing the 102 (b) rejection in the office action of October 22, 2003.

Claims 1-3, 5-32, 34-37 and 76-80 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hyong for the reasons set forth on page 2 of the office action of May 7, 2003.

Claims 1-3, 5-32, 34-37 and 76-80 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on page 2 of the office action of October 22, 2003.

Applicant's arguments and remarks regarding 102 (b) rejection have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks refers to pages 10 and 11, tables 2.3 and 2.4 of the specification. Applicant alleges criticality to the significant IOP reduction in patients with sever glaucoma in comparison to the individuals who do not suffer from sever IOP. The allegation is not well taken. The presented data in the specification do not demonstrate a "significant" IOP reduction in patients with sever glaucoma over the ones with normal glaucoma. Furthermore, the presented data are not commensurate in scope with the claimed language. Applicant has used one prostaglandin derivative and one beta-adrenergic antagonist, however, the claims are not limited only to those two compounds. Applicant's arguments and remarks regarding the 112 first paragraph have also been carefully considered, but are

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not deemed to be persuasive. The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1968 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089, 118 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") guidelines for Examination of Patent Applications under the 35 U.S.C. 112. "Written Description" requirement ("Guidelines"). 66 Fed Reg. 1099 (Jan.5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,"including, inter alia' functional characteristics when coupled with a known or disclosed correlation between function and structure "Enzo biochem, inc.v.Gen-probe inc., 296 F.3d, 316, 1324-25 (Fed. Cir 2002) (quoting guideline, 66 Fed. Reg. At 1106 (emphasis added. Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structure in general. Univ. of Rochester V. G.D. searle & co., 249 F.supp.2d 216, 225 (W.D.N.Y. 2003).

Applying the reasoning of the above-cited case law to facts at hand, the instant specification fails to provide an adequate written description of suitable prostaglandin

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derivatives, beta-adrenergic antagonists and carbonic anhydrase inhibitors. The specification describes only a limited number of such agents. The instant claims generally recite a prostaglandin derivative, a beta-adrenergic antagonist and a carbonic anhydrase inhibitor. When functional claims are drawn this broadly, they are inclusive of any prostaglandin derivative, any beta-adrenergic antagonist and any carbonic anhydrase inhibitors, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structures. The instant specification quite simply, discloses a few compounds within the scope of the claimed language. As such, it cannot possibly provide any direction for using any peptides, peptide mimetics, or RNA-DNA based structure; no identifying characteristics of any kind, e.g. sequences, are provided. Accordingly, the instant specification fails to provide an adequate written description.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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